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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
D-0021.5C-1

I hereby certify that this paper and the documents referred to as attached therein are being facsimile transmitted to the U.S. Patent and Trademark Office on the date shown below.

on December 12, 2006

Signature Denise Ortega

Typed or printed name Denise Ortega

Application Number	Filed
09/807,949	August 9, 2001

First Named Inventor
Jan Zavada

Art Unit	Examiner
1643	Christopher Yaen

Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 30,863
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____

Signature

Leona L. Lauder
Typed or printed name

415-981-2034
Telephone number

December 12, 2006
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☑ *Total of 1 forms are submitted.

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Jan Zavada et al.

Serial No.: 09/807,949 Group Art Unit: 1643

Filed : August 9, 2001 Examiner: Christopher H. Yaen

For : MN Gene and Protein

REQUEST FOR PRE-APPEAL BRIEF CONFERENCE

MAIL STOP AF
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

REMARKS

The following arguments are provided in support of a Request for Pre-Appeal Brief Conference in Application No. 09/807,949.

Claims currently pending in the application are Claims 31-37, 39, 41 and 42, directed to a method of identifying a molecule that specifically binds to the cell adhesion site of the MN/CA IX oncoprotein. Applicants respectfully submit that the two 35 USC §112, ¶1 rejections of Claims 31-37, 39, 41 and 42 in the Final Office Action mailed from the PTO on October 13, 2006 ["Final Office Action"] are improper and without basis.

I. First 35 USC §112, ¶1 Rejection is Improper: Use of Formal Markush Group Language

Applicants respectfully submit that the first 35 USC §112, ¶1 rejection of the Final Office Action is improper as it constitutes a rejection of standard Markush group claim language in independent Claim 31. Applicants respectfully submit that the

phrase at issue from the first paragraph of Claim 31 -- "wherein said site's amino acid sequence comprises an amino acid sequence selected from the group consisting of SEQ ID NOS.: 10 and 98-103 . . ." (emphasis added) -- is formal Markush group claim language that inherently refers to the full-length amino acid sequence of one of a group of amino acid sequences identified by SEQ ID NOS., and would **not** be understood by ones of skill in the art to include within said group "a fragment as small as two amino acids . . ." from within one of the listed amino acid sequences, as argued by the Examiner in the April 24, 2006 Office Action at page 7, and in the Final Office Action at pages 2-3.

Applicants' arguments to the subject 112, ¶ 1 rejection can be found in Applicants' July 24, 2006 response, at pages 21-25, including footnotes 4 and 5 at pages 23 and 24. Original support in the Specification is cited in Applicants' response dated February 2, 2006, at pages 16-19, including the Table of SEQ ID NOS. at pages 18-19 of that response.

Applicants further respectfully point out that there is no antecedent basis in Claim 31 for the amendment proposed by the Examiner, that is, "**the** amino acid sequence," and that said Examiner proposed amendment could be construed to add ambiguity to Claim 31. That ambiguity issue is explained in Applicants' July 24, 2006 response at page 23 (middle full paragraph and footnote 4).

Applicants respectfully conclude that the instant 112, ¶ 1 rejection of all the pending claims is a rejection of formal Markush group claim language, and is improper and without basis.

II. Second 35 USC §112, ¶1 Rejection is Improper: Rejection of Inherent Characterization as New Matter

Applicants respectfully submit that the second 35 USC §112, ¶1 rejection of the Final Office Action is improper as a "new matter" rejection of subject matter that is not "new matter" but instead constitutes a negative limitation clearly inherent in the Specification. Applicants respectfully point out that it is axiomatic that the clarification of inherent characterization does not add new matter to an application. [See, for example, In re Smythe, 178 USPQ 279 (CCPA 1973).]

The instant 35 USC §112, ¶1 rejection is based on a finding of lack of literal support in the Specification for a proviso added to the end of Claim 31, and perhaps on a misunderstanding:

> Applicant's [sic] have amended the claims to include a negative proviso limitation of "the non-MN-portion of said fusion protein or said fusion polypeptide does not contain a cell adhesion site". Applicant directs the examiner to page 21, lines 1-14 and page 69, lines 8-13 for support of this new limitation. However, the pages direct [sic] are drawn to the explanation of why the fusion protein would contain an additional binding site to which cells could potentially bind. There is no specific indication or disclosure that support a negative limitation or specific exclusion of fusion proteins missing a cell adhesion site as now currently claimed.

[Final Office Action, page 3, Section 5.] Applicants respectfully respond that the addition of the proviso at the end of Claim 31 only makes explicit what one of skill in the art would understand from the implicit teachings of the Specification.[1]

The MPEP at §2163.07(a) makes clear that a specification is interpreted according to what one of ordinary skill in the art would understand is supported both explicitly and implicitly, and that the claims may be amended accordingly without adding new matter:

> By disclosing in a patent application a device that inherently performs a function, operates according to a theory or has an advantage, a patent application necessarily discloses that function, theory or advantage, even though it says nothing explicit concerning it. The application may later be amended to recite the function, theory or advantage without introducing the prohibited new matter. *In re Reynolds* . . . 170 USPQ 94 (CCPA 1971); *In re Smythe* . . . [cited supra] (CCPA 1973).

As the PTO Board of Patent Appeals and Interferences stated in Ex parte Soreson, 3 USPQ2d 1462 (Bd. Pat. App. & Interf. 1987) at page 1463:

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1. "To comply with the written description requirement of 35 USC 112, para. 1, . . . each claim limitation must be expressly, implicitly, or inherently supported in the originally filed disclosure." [MPEP §2163.05, page 181.]

> [W]e are mindful that appellant's specification need not describe the claimed invention in *ipsis verbis* to comply with the written description requirement. . . . The test is whether the originally filed specification disclosure *reasonably* conveys to a person having ordinary skill that applicant had possession of the subject matter later claimed. . . .

[Emphasis in original.]

Regarding negative limitations, the MPEP at §2173.05(i) requires only that

> [a]ny negative limitation or exclusionary proviso must have basis in the original disclosure. . . . [A] lack of literal basis in the specification for a negative limitation may not be sufficient to establish a *prima facie* case for lack of descriptive support. *Ex parte Parks*, 30 USPQ2d 1234, 1236 (Bd. Pat. App. & Inter. 1993).

There is a clear basis in the original Specification for the proviso at issue. The passage at page 69, lines 8-13 of the Specification, cited by Applicants as support for the proviso of Claim 31, teaches that the use of the MN fusion protein GST-MN in previous experiments had masked the identification of MN's cell adhesion site and had led to incorrect conclusions, because the inventors had not realized that the "GST [glutathione-S-transferase] anchor itself contains another binding site, which is not blocked by M75." [Specification at page 69, lines 12-13. M75 is a monoclonal antibody that specifically binds MN protein at its cell adhesion site.] The GST-MN fusion protein is then expressly described in the Specification as an inoperative embodiment that renders useless a cell adhesion assay to detect molecules that bind MN's cell adhesion site, in that the MN fusion protein's non-MN portion "itself contains another binding site, which is not blocked by M75." [*Id.*]

Ones of skill in the art would then understand from the Specification that any non-MN portion of a MN fusion protein/polypeptide used in the claimed cell adhesion assays could not contain its own cell adhesion site for the cell adhesion assay to be effective to detect molecules that bind to MN's cell adhesion site. Ones of skill in the art could predict from the Specification [particularly at page 69, lines 8-13] that, if the MN fusion protein GST-MN did not work in the claimed assay because the GST portion of it contained its own binding site, then any other MN fusion protein containing a

second, non-MN cell adhesion site would also not work in the claimed assay. The proviso at issue simply expresses that understanding.

The Specification teaches that if a MN fusion protein/polypeptide is used in a MN cell adhesion assay, the non-MN portion of the fusion protein needs to be tested to assure that it does not contain a cell binding site. Applicants respectfully direct attention to the Remarks in their response dated July 24, 2006, at pages 8-11, which support the addition of the proviso at issue. By the addition of the proviso to the end of Claim 31, Applicants are only making explicit what one of skill in the art would understand from the implicit teachings of the Specification: that an MN fusion protein containing a second, non-MN protein-derived cell adhesion site would not be useful to screen for molecules that bind to MN's cell adhesion site.

For the reasons provided above, Applicants respectfully conclude that the second 35 USC §112, ¶1 rejection of all the pending claims is improper and without basis.

III. Conclusion

In view of the above considerations, Applicants respectfully request a Pre-Appeal Brief Conference to review the legal and factual bases of the subject two 112, ¶ 1 rejections.

Respectfully submitted,

Leona L. Lauder
Attorney for Applicants
Registration No. 30,863

Dated: December 13, 2006